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10/771,388	02/05/2004	Horst Georg Zerbe	2004-0189	3058
<div>7590 12/01/2009</div> <div>Michael R. Davis WENDEROOTH, LIND & PONACK Suite 800 2033 "K" Street N.W. Washington, DC 20006-1021</div>				
EXAMINER				
ROBERTS, LEZAH				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/771,388

Applicant(s)

ZERBE ET AL.

Examiner

LEZAH W. ROBERTS

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2009.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-29, 31 and 33-61 is/are pending in the application.
4a) Of the above claim(s) 41-51 is/are withdrawn from consideration.
5) ☒ Claim(s) 10-23, 57 and 58 is/are allowed.
6) ☒ Claim(s) 24-29, 31, 33-36, 38-40, 52-56 and 59-61 is/are rejected.
7) ☐ Claim(s) 37 and 54 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed July 2, 2009 and in the Request for Continued Examination filed September 3, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Objections

Claim 54 is objected to because of the following informalities: the claims comprises two periods at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejections)

1) Claims 24-29, 31, 33-36, 38-40, 52-56 and 61 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554) in view of Stanley et al. (US 5,783,207). The rejection is withdrawn in regard to claim 57.

Applicant's Arguments

Applicant argues Majeti discloses neither nicotine salts nor hydroxypropylmethyl cellulose (present claim 28), nor a composition comprising a combination of polyvinyl pyrrolidone and hydroxypropylmethyl cellulose as essential components (present claim 28) and remains silent as regards the solubility properties of the compositions described in this patent. Further, Majeti fails to teach hydroxypropylmethyl cellulose (HPMC) which in the Examiner's view is interchangeable with hydroxypropylcellulose (HPC). Acharya (US 5,686,094, referred to by Examiner) pertains to water-containing delivery devices, whereas Majeti's compositions are not water-containing. Therefore, Acharya does not support the notion that HPMC and HPC would represent equivalents when used in Majeti's compositions. Further, Acharya mentions neither nicotine nor nicotine salts. Hence, the prior art would not have recognized HPMC and HPC as equivalents in compositions containing nicotine or nicotine salts. Majeti's teaching is specifically concerned with compositions containing nicotine base as the active ingredient. Therefore, the skilled person would have assumed that the components (e.g. polymers) taught by Majeti were selected so as to be compatible with nicotine base (rather than nicotine in salt form). Applicants further submit that Majeti fails to teach the specific combination of flavoring agents, sweeteners and tartaric acid recited in claim 24, in a

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monolayer film containing nicotine salts. While Stanley et al. generally mention flavorings and flavor enhancers; the reference does not teach or suggest the combination of items iii, iv and v of present claim 24. Furthermore, while it was recognized by Majeti that nicotine has a characteristic odor, this reference fails to indicate which fragrances might be useful for suppressing the unpleasant odor of nicotine. The present invention avoids or alleviates this problem by employing nicotine salts rather than nicotine base, and by combining these nicotine salts with a combination of flavoring agents, sweeteners and flavor enhancing agent as defined in claim 24. Since the specific substances used for this purpose (menthol, mint flavor, aspartame, sorbitol, tartaric acid) were not even mentioned by Majeti, the selection of these components - according to the present invention - cannot be regarded obvious in view of the cited prior art.

Examiner's Response

Although Majeti does not disclose hydroxypropylmethyl cellulose, it does disclose hydroxypropyl cellulose which has been disclosed in the art as equivalents. Further Majeti discloses cellulose derivatives are suitable for the compositions. Further the compositions of Majeti may include solvents, which include water. Thus it may be concluded that the polymers used in the supporting document are suitable in the compositions of Majeti. Although the supporting document of Acharya does not disclose nicotine, it does disclose active agents are incorporated into the films. In regard to the

time of dissolution, although the reference is silent in regard to this property, it discloses an example of a single layer composition comprising two water soluble polymers. It is reasonable to conclude these films dissolve similar to those recited in the claims or have rapid dissolution, especially considering the claims do not recite a specific time of dissolution, see indefinite rejection supra. Further nicotine salts are more stable than nicotine base, thus it is reasonable to conclude that components compatible with nicotine base would also be compatible with nicotine salts.

The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See MPEP 2144, IV. Applicant asserts that employing nicotine salts rather than nicotine base suppress the unpleasant odor of nicotine. The references teach nicotine salt is more stable than nicotine base, and therefore there is motivation to use the salt in place of the base. Therefore, it is reasonable for one of ordinary skill in the art to arrive at the instant invention without the same motivation to combine the two references. In regards to the flavorings, Majeti discloses flavorings are suitable in the compositions and Arachaya discloses tartaric acid is a flavoring and therefore it is reasonable to use flavorings known in the art. Majeti discloses using sorbitol and menthol which suggest using these components in the compositions.

2) Claims 59 and 60 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554) in view of Stanley et al. (US 5,783,207) in further view of Dam (US 5,733,574).

Applicant's Arguments

Applicant argues Dam does not relate to film compositions. While there is no doubt that caramel will produce a brown color when admixed to thick compositions, the same would not be expected in the case of thin films having a thickness of not more than 70 μm . Also, according to Dam's teaching, caramel was used only in combination with gelling agents such as gelatin, agar, alginate, etc. Since caramel is a product whose chemical structure is essentially unknown (caramel is produced by heating sugar above its melting point), it was unpredictable whether this substance would be compatible with the specific polymer components recited in present claim 28, polyvinyl pyrrolidone and hydroxypropylmethyl cellulose.

Examiner's Response

Caramel has a brown color. It is reasonable to conclude that when added to a solution that that solution would take on some brown characteristic. Further caramel is disclosed as a color additive and therefore should act as a coloring agent no matter the thickness of the compositions. It is also reasonable to conclude that if it colors a thick composition that it will color produce a brown tint in one that is much thinner.

Allowable Subject Matter

Claims 10-23, 57 and 58 are allowed.

Claim 37 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Claims 10-23, 37, 57 and 58 overcome the previously applied prior art rejections and appear to be distinct over the prior art. The claims recite a specific combination of 2 to 4 classes of surfactants. These include a mixture of at least two non-ionic surfactants, wherein the first surfactant is chosen from a polyoxyethylene sorbitan fatty acid ester and alpha-hydroxy-omega-hydroxypoly(oxyethylene)-poly(oxypropylene)poly(oxyethylene) block copolymer and the second is a polyoxyethylene alkyl ether or a polyoxyethylene castor oil. At the effective filing date of the instant application, the combination and the reason to use such a combination do not appear to be taught in the prior in relation to a monolayer film comprising an active deliverable via a mucous membrane, specifically nicotine or its salts, specifically a monolayer film that softens immediately or has a rapid dissolution or disintegration rate. Although combinations of surfactants are used in the art, it has been disclosed these are

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used for drugs that are generally hydrophobic and need to be solubilized to enhance their delivery. Nicotine and its salts are water-soluble and one of ordinary skill in the art would not be motivated to use a mixture of surfactants to enhance their delivery. Thus, one of ordinary skill in the art would not be motivated to add such a combination of surfactants to a rapidly disintegrating monolayer film to deliver a pharmaceutically active agent that is deliverable via a mucous membrane, based on the prior art.

It is suggested Applicant insert claim language to indicate that the film is a dry film to distinguish the film from a solution that may be applied to a surface as a single layer. This would further support that the monolayer film is a film that when introduced to the oral cavity will soften due to the moisture in the mouth and dissolve or disintegrate.

Claims 24-29, 31, 33-36, 38-40, 52-56 and 59-61 are rejected.

Claims 37 and 54 are objected.

Claims 10-23, 57 and 58 are allowed.

Claims 41-51 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612
/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612